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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,294	11/22/2006	Debbie Stevens-Wright	B1075.71016US01	1798

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EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	PAPER NUMBER
3739	
MAIL DATE	DELIVERY MODE
10/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,294	STEVENS-WRIGHT, DEBBIE	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12,14-16,20,23-25,27,30,34,35,38,91 and 92* is/are pending in the application.

4a) Of the above claim(s) *34 and 35* is/are withdrawn from consideration.

5)☒ Claim(s) *5 and 6* is/are allowed.

6)☐ Claim(s) *1-4,7-10,12,14-16,20,23-25,27,30,38,91 and 92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's amendments and comments, received June 17, 2009, have been fully considered by the examiner. The following is a complete response to the June 17, 2009 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1-4, 7-10, 12, 14-16, 20, 23-25, 27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rittman, III et al (6,575,969) in view of the teaching of Jain et al ("A Three-Dimensional Finite Element Model of Radiofrequency Ablation with Blood Flow and its Experimental Validation").

Rittman discloses a system that receives signals of various operating parameters and utilizes those signals to affect control of the operating parameters of the RF generator. In particular, Rittman discloses that fluid is delivered to tissue, and that flow rate, temperature and impedance signals are fed back to a controller. Figure 7 specifically shows the temperature, power and fluid flow signals provided to the controller (709) which then controls the output power of the RF generator (707). Column 12, lines 30-43 specifically discloses the use of impedance measurement as a feedback signal for controlling the output of the generator. Rittman also specifically disclose real-time imaging for providing a signal to the controller to control generator outputs (col. 14). The images in real time show a display of the probe with respect to the ablation lesion being created and the size of the tumor, and thus provide a signal representing a distance from the ablation electrode to the target tissue (i.e. from the

electrode tip to the tumor tissue that has not yet been ablated). Rittman teach the use of various algorithms, finite modeling and other calculations for receiving all this information, processing the information and formulating an output for the generator (col. 14, lines 10-22). The geometry of the electrode is also taken into consideration by the controller (col. 12, lines 30-40). While Rittman, III et al disclose the use of a flow sensor, there is no disclosure of using a blood flow rate as a feedback for selecting an operating parameter.

As addressed in the previous Office action, Jain et al teach in the article that it is generally known that blood flow provided around a probe effects the cooling of an RF electrode, and that it is advantageous to provide a feedback signal of the blood flow around a probe in order to more accurately control the temperature of an RF probe in the body.

To have provided the Rittman system with a blood flow sensor to monitor blood flow around the probe and to more accurately control the delivery of RF energy to the probe would have been an obvious consideration for the skilled artisan in view of the teaching of Jain et al.

Claims 1, 2, 9, 10, 12, 14-16, 23-25, 30, 38, 91 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoey et al (6,409,722) in view of the teachings of the articles to Zhang et al ("Noncontact Radio-Frequency Ablation for Obtaining Deeper Lesions") and Jain et al ("A Three-Dimensional Finite Element Model of Radiofrequency Ablation with Blood Flow and its Experimental Validation").

Hoey et al disclose another system that provides various feedback data to control the output of an RF ablation device. Specifically, Hoey et al disclose a flow sensor and an impedance and temperature feedback system to provide feedback to a controller to control the output parameters of the electrosurgical generator. The output power, voltage, current and the flow rate may all be controlled based on sensed conditions (Abstract). Hoey et al fail to teach providing a signal related to the distance of the ablation electrode from tissue as part of the feedback data used to control the energy output.

Zhang et al teach that it is generally known to vary fluid flow rates and energy from the generator based on the distance of the electrode from the tissue being treated (see Abstract). The distance was maintained using spacers to provide a desired distance from the electrode to the tissue in a non-contact ablation procedure. The user would select the desired spacing when setting the output for the generator for the procedure.

To have provided the Hoey et al system with a spacing element to provide for non-contact ablation of a target tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Zhang et al. To have further provided the specific spacing used as an input to the controller to control the output parameters of the system would have been an obvious consideration, particularly since Zhang et al teach that it is known to vary output parameters based on the fluid flow rate and distance of the electrode from tissue.

Claims 3, 4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoey et al (6,409,722) in view of the teaching of the article to Zhang et al ("Noncontact Radio-Frequency Ablation for Obtaining Deeper Lesions") and further in view of the teaching of Rittman, III et al ('969).

While it would be intuitive to use algorithms and/or finite element modeling to arrive at the specific relationships between the various feedback parameters and the generator output of the Hoey et al system, there is no express disclosure in Hoey of using such an analysis in generating the output relationships between the generator and the feedback signals.

Rittman, as addressed previously, disclose an analogous RF ablation system that includes a controller that receives various input signals and correlates the input signals into desired output parameters for the RF generator. In particular, Rittman teach of using various algorithms, finite modeling and other relationships for correlating the output parameters of the RF generator to the input signals (col. 14, lines 10-22).

To have provided the Hoey et al system, as modified by the teaching of Zhang et al, with an algorithm or modeling program to correlate the generator output to the received feedback signals would have been an obvious modification for one or ordinary skill in the art since Rittman fairly teaches it is generally known to use such algorithms and modeling in an analogous system.

Response to Arguments

Applicant's arguments filed June 17, 2009 have been fully considered but they are not persuasive.

Regarding claim 1, applicant asserts that Rittman fails to disclose receiving a signal representing a value of a positive distance from an ablation electrode surface to a target tissue surface. The examiner disagrees. There is no disclosure in applicant's specification that the only way to measure a "positive distance" is via an electrode located outside a tumor. That is, while the specification makes reference to a "positive distance" as being relative to an electrode that is not embedded in tissue, that does not preclude the phrase "positive distance" as being more broadly interpreted. The examiner maintains that the outer surface of a tumor may be deemed a "target tissue surface", and that the distance from the embedded electrode to the outer surface of the tumor may be deemed a "positive distance". Moreover, applicant's specification makes clear that there is no critical distinction between using a "positive distance" for the electrode or using an electrode that is embedded. The examiner maintains that using an electrode in either modality would be an obvious consideration for the skilled artisan as the skilled artisan would recognize that the electrode may be used in any desired tissue location as necessary. Also, it is noted that claim 1 has been amended to recite the limitation of using a signal related to blood flow rate. The examiner has thus applied the Jain et al article as a teaching of using blood flow rate as a feedback signal in controlling the setting of operating parameters. Applicant has not substantively argued this rejection, which was applied to previously pending claim 29 in the previous Office action. The Jain et al reference was also added to the rejection involving the Hoey et al reference as the Jain et al teaching is equally applicable to that rejection.

Regarding claim 38, Applicant asserts that Hoey in view of Zhang fails to disclose a signal representing a blood flow rate. As asserted above, the examiner has added the Jain et al reference to the rejection as Jain et al clearly disclose the use of blood flow rates as a feedback signal to control RF energy delivery to a probe.

Allowable Subject Matter

Claims 5 and 6 are allowed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jain et al (2002/0169445) disclose an RF ablation system that uses, among other parameters, blood flow rate as a feedback signal to control output values of the RF system.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
October 8, 2009